



1103326-0072

#19

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Lindberg et al.
Serial No. : 09/690,044
Filed : October 16, 2000
For : NEW COMPOUNDS
Examiner : J. Fan
Group Art Unit : 1625

CERTIFICATE OF TRANSMISSION UNDER 37 CFR §1.8

I hereby certify that this paper is being deposited
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John M. Genova 32,224
Attorney Name PTO Reg. No.

John M. Genova 23 December 2003
Signature Date of Signature

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Assistant Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT
FILED CONCURRENTLY WITH
REQUEST FOR CONTINUED EXAMINATION (37 C.F.R. §1.114(a)(1))**

Sir:

A Request for Continued Examination pursuant to 37 C.F.R. §1.114(a)(1) is being
submitted concurrently with this Information Disclosure Statement ("IDS"). Applicants submit
this IDS in compliance with 37 C.F.R. §§1.56, 1.97 and 1.98. Consideration of the patentability

of the claimed invention in view of the documents listed on Form PTO-1449 attached hereto is respectfully requested.

REMARKS

Claims 1 and 32 are the only two claims pending in the referenced U.S. Patent Application Serial No. (the "'044 application"). A Notice of Allowance was issued in the '044 application on 10 October 2003. The Issue Fee due date is 12 January 2004. The Issue Fee has not been paid.

Applicants submit this IDS for the purpose of making of record an opposition proceeding before the European Patent Office ("EPO") that had been filed against the European patent belonging to the same patent family as the referenced '044 application. The European patent was filed as European Patent Application 94917244.9-2117 (the "EP application"), which issued as European Patent No. 0 652 872 on 8 November 2000 (the "EP patent"). The EP application is a regional application derived from international application No. PCT/SE94/000509, filed 27 May 1994, which claims priority to SE 9301830-7, filed 28 May 1993. The referenced '044 application originates from the same priority and PCT applications.

The opposition was filed on 18 July 2001 by Ratiopharm GmbH and, in accordance with the relevant local rules, certain third party observations were submitted in support of the opposition on 30 May 2002 by an anonymous party that was not a party to the opposition proceedings. Subsequently, the parties to the opposition, i.e., the opponent Ratiopharm and the applicant AstraZeneca, filed submissions in support of their respective positions. The opposition proceedings addressed the patentability, *inter alia*, of those claims of the EP patent which correspond to compound claims 1 and 35 of the '044 application.

An Oral Hearing before the EPO Opposition Panel took place on 25 November 2003 and a final decision upholding the patentability of claims 1-15 of the EP patent was announced by the EPO Opposition Panel on the same day.

As part of this IDS, Applicants submit two separate binders of publicly available documents relating to the European opposition proceedings. One binder contains patent and technical publications which are identified as documents ##1-26. These documents were submitted by the parties in the opposition proceedings. Each of documents ##1-26 is listed on the attach PTO-Form 1449. Several of the documents are in German and have not been translated. As discussed below in more detail, the parties in the opposition proceedings and the EPO Opposition Panel undertook a consideration of the materiality of documents ##1-26 and agreed that document #2, EP 0 124 495 ("EP '495), and document #3, DE 40 35 455 ("DE '455"), are the most material to the patentability of the claimed invention of the EP patent. Therefore, Applicants submit that a translation of the German language documents is not required since the conclusion of the EPO Opposition Panel is a concise explanation of the relevance of the non-English language documents in satisfaction of 37 C.F.R. §1.98(a)(3)(i).

The second binder contains a copy of the EP patent (#1) and copies of the various written submissions made by the parties to the opposition proceedings. The second binder also contains a copy of a formal notice of the decision of the EPO Opposition Panel upholding the patentability of claims 1-15 of the EP patent (#9). Each of these documents is also listed on the attach PTO-Form 1449. Applicants will submit a supplemental IDS to make of record the formal written decision of the EPO Opposition Panel as soon as the decision has been issued and is available.

As previously mentioned, EP '495 and DE '455 were held to be the most relevant prior art documents in the opposition proceedings. It is expected that this holding will be stated in the written decision of the EPO Opposition Panel. EP '495 belongs to the same patent family as US 4,738,974, issued 19 April 1988 (the "'974 patent"). The '974 patent and DE '455 were cited in support of claim rejections under §§102 and 103 in the referenced '044 application and related prior applications. The claim rejections based on the '974 patent and DE '455 were eventually withdrawn and the subject '044 application proceeded to allowance.

In view of the foregoing, Applicants submit that the decision of the EPO Opposition Panel confirms that '974 patent and DE '455 are the most material prior art to the claimed invention and that the remaining documents submitted by this IDS, e.g., documents ##1 and 4-26 of Binder 1, are less material to patentability or are cumulative at best.

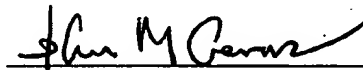
Applicants respectfully request the Examiner's consideration of this IDS and issuance of a Notice of Allowance for the reasons of record.

TIME OF TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

The Information Disclosure Statement transmitted herewith is being filed concurrently with a Petition under 37 C.F.R. §1.313(c) and Request for Continued Examination and therefore no separate fee is due. However, authorization is hereby given to charge Account No. 23-1703 for any fee which may be due in connection with this communication.

Dated: 23 December 2003

Respectfully submitted,



John M. Genova
Reg. No. 32,224
Attorney for Applicants

Customer No. 007470
Attorney Direct Dial: (212) 819-8832



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PTO/SB/08A (08-03)

Use for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	09/690,044
Filing Date	October 16, 2000
First Named Inventor	Per Lennart Lindberg
Art Unit	1625
Examiner Name	Fan, Jane T.
Attorney Docket Number	1103326-0072

Sheet 1 of 3

FOREIGN PATENT DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
	D1-Binder 1.	EP-0 005 129 A1	10-31-1979			
	D2-Binder 1.	EP-0 124 495 A2	11-07-1984			
	D3-Binder 1.	DE-40 35 455 A1	05-14-1997			
	D10-Binder 1.	EP-01.662 87.B1	01-02-1986			
	D12-Binder 1.	WO 88/03921(Page 35)	06-02-1988			
	D1-Binder 2	EP-0 652 872	05-17-1995			

NON PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	D4-Binder 1.	J. MARCH, Advanced Organic Chemistry, 4 th edition (1992), John Wiley & Sons, pages 100, 120, 121, 378 and 379.	
	D5-Binder 1.	A. PILBRANT and C. CEDERBERG, "Development of an oral formulation of omeprazole", Scandinavian Journal of Gastroenterology, Volume 20, Supplement 108 (1985), pages 113-120.	
	D6-Binder 1.	Beyer-Walter, Lehrbuch der Organischen Chemie [Textbook of organic chemistry], 22 nd edition (1991), S. Hirzel Verlag, Stuttgart, pages 735-736.	
	D7-Binder 1.	H.J. FEDERSEL, "Chiral Arzneimittel", Chemie in unserer Zeit (1993)/No. 2, VCH Verlagsgesellschaft mbH, pages 78-87.	
	D8-Binder 1.	D. ENDERS and R.W. HOFFMANN, "Asymmetrische Synthese", Chemie in unserer Zeit (1985)/No. 6, VCH Verlagsgesellschaft mbH, pages 177-190.	
	D9-Binder 1.	Clinical studies A and B by Astra Hässle AB, introduced into the grant proceedings.	
	D11-Binder 1.	Methoden der Organischen Chemie (Houben Weyl) [Methods of organic chemistry, Houben Weyl], volume I/1, 1958, chapter "Crystallization", pages 345-389.	
	D13-Binder 1.	P. LINDBERG <i>et al.</i> , "Omeprazole: The First Proton Pump Inhibitor", Medicinal Research Reviews, Vol. 10, No. 1, 1-54 (1990).	
	D14-Binder 1.	P. ERLANDSSON <i>et al.</i> , "Resolution of the enantiomers of omeprazole and some of its analogues by liquid chromatography on a trisphenylcarbamoylcellulose-based stationary phase: The effect of the enantiomers of omeprazole on gastric glands", Journal of Chromatography 532 (1990) 305-319.	
	D15-Binder 1.	W. FORTH <i>et al.</i> , "Allgemeine und spezielle Pharmakologie und Toxikologie" [General and special pharmacology and toxicology], Wissenschaftsverlag, 6 th edition 1992, pages 33, 34, 55-57, 70, 472 and 473.	
	D16-Binder 1.	M. EICHELBAUM <i>et al.</i> , "Effects of Verapamil on P-R-Intervals in Relation to Verapamil Plasma Levels Following Single i.v. and Oral Administration and During Chronic Treatment, Klinische Wochenschrift 58, 919-925 (1980).	

Examiner Signature

Date Considered

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with new communication to applicant. ²Applicant's unique citation designation number (optional). ³See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ⁴Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁵For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁷Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORM TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	09/690,044
Filing Date	October 16, 2000
First Named Inventor	Per Lennart Lindberg
Art Unit	1625
Examiner Name	Fan, Jane T.
Attorney Docket Number	1103326-0072

Sheet 2 of 3

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	D17-Binder 1	P. DAYER <i>et al.</i> , "Interindividual Variation of Beta-Adrenoceptor Blocking Drugs, Plasma Concentration and Effect: Influence of Genetic Status on Behavior of Atenolol, Bopindolol and Metoprolol, Eur. J. Clin. Pharmacol. (1985) 28(2): 149-153.	
	D18-Binder 1	"The result of a recent study comparing all PPI's currently on the market".	
	D19-Binder 1	P. FRESENIUS, "Organic Chemical Nomenclature, Introduction to the Basic Principles", Ellis Horwood Limited, page 127.	
	D20-Binder 1	S. YAMADA and S. NARITA, "Synthesis and Isomerization of Optical Active 2[(6,7,8,9-tetrahydro-5H-cyclohepta[b]pyridin-9-yl)sulfinyl]-1H-benzimidazole Analogs" Chem. Pharm. Bull 42(8), 1679-1681 (1994).	
	D21-Binder 1	JACOBUS <i>et al.</i> , "Racemization and Cleavage of Sulfoxides by Methylolithium", Journal of the American Chemical Society 89:20; pages 5228-5234 (1967).	
	D22-Binder 1	TANAKA, M. <i>et al.</i> , "Direct Determination of Pantoprazole Enantiomers in Human Serum by Reversed-Phase High-Performance Liquid Chromatography Using a Cellulose-Based Chiral Stationary Phase and Column-Switching System as a Sample Cleanup Procedure", Analytical Chemistry, Vol. 68, No. 9, 1513-1516 (1996)	
	D23-Binder 1	CASS <i>et al.</i> , "Enantiomeric determination of pantoprazole in human plasma by multidimensional high-performance liquid chromatography", J. Chromatography B, 766 (2001) 153-160.	
	D24-Binder 1	Comprehensive Medicinal Chemistry, Pergamon Press (1990), Volume 2, pages 193- 205.	
	D25-Binder 1	RENNBERG <i>et al.</i> , "Identification of Two Main Urinary Metabolites of [¹⁴ C]Omeprazole in Humans", Drug Metabolism and Disposition, Vol 17, (1989) 69-76.	
	D26-Binder 1	Abstract #35, "Synthesis and Biological Activity of Enantiomers of H ⁺ K ⁺ -ATPase Inhibiting 2-(2-Pyridylmethyl) sulphinyl-benzimidazoles (PSBs) from Program of the Fourth International Symposium of Chiral Discrimination, 19-22 September 1993, Montreal, Quebec, Canada.	
	D2-Binder 2	In the matter of EP 0 652 872, Notice of Opposition and Opposition Brief in the name of Ratiopharm GmbH, dated 18 July 2001.	X
	D3-Binder 2	In the matter of EP 0 652 872, Response to the Opposition Brief by AstraZeneca AB, dated 27 March 2002.	
	D4-Binder 2	In the matter of EP 0 652 872, third party observations, dated 30 May 2002.	
	D5-Binder 2	In the matter of EP 0 652 872, opponent submission, dated 22 January 2003.	X
	D6-Binder 2	In the matter of EP 0 652 872, summons to oral proceedings, dated 15 July, 2003.	
Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORM TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

BINDER 1

D1	EP 0 005 129 A1
D2	EP 0 124 495 A2
D3	DE 40 35 455 A1
D4	J. March, Advanced Organic Chemistry, 4 th edition, 1992, John Wiley & Sons, pages 100, 120/121 and 378/379"
D5	A. Pilbrant, C. Cederberg, Development of an oral formulation of omeprazole, Scandinavian Journal of Gastroenterology, 1985, 20, 113-120
D6	Beyer, Walter, Lehrbuch der Organischen Chemie [Textbook of organic chemistry], 1991, S. Hirzel Verlag, Stuttgart, 22 nd edition, pages 735-6.
D7	H.J. Federsel, Chemie in unserer Zeit, 1993, No. 2, 78-87.
D8	D. Enders, R.W. Hoffmann, Chemie in unserer Zeit, 1985, No. 6, 177-190.
D9	Clinical studies A and B by Astra Hässle AB, introduced into the grant proceedings.
D10	EP 0 166 287 B1
D11	Methoden der Organischen Chemie (Houben Weyl) [Methods of organic chemistry, Houben Weyl], volume I/1, 1958, chapter "Crystallization", pages 345-389.
D12	Page 35 of WO 88/03921
D13	P. Lindberg <i>et al.</i> In "Omeprazole: The First Proton Pump Inhibitor", Medicinal Research Reviews 10 (1990) 1-54.
D14	P Erlandsson <i>et al.</i> , in Journal of Chromatography 532 (1990) 305-319.
D15	W. Forth <i>et al.</i> : "Allgemeine und spezielle Pharmakologie und Toxikologie" [General and special pharmacology and toxicology], Wissenschaftsverlag, 6 th edition 1992, pages 33/34, 55-57, 70 and 472/473.
D16	M. Eichelbaum <i>et al.</i> Klin. Wochenschr. 1980 Sep 15;58(18): Abstract.
D17	P. Dayer <i>et al.</i> , Eur. J. Clin. Pharmacol. 1985;28(2): Abstract
D18	"The result of a recent study comparing all PPI's currently on the market"
D19	Fresenius "Organic Chemical Nomenclature".
D20	S. Yamada and S. Narita, Chem. Pharm. Bull 42, 1679 to 1681 (1994)
D21	Jacobus <i>et al.</i> JACS (1967) 5228.
D22	Anal. Chem. 1996, 68, 1513-1516.
D23	Cass <i>et al.</i> J. Chromatography B (2001) 153.
D 24	Extract from Comprehensive Medicinal Chemistry, page 205.
D25	Renberg <i>et al.</i> Drug Metabolism and Disposition (1989) 69.
D26	Abstract conference 19-22 September 1993

BINDER 2

x

1	EP 065 28 72 AstraZeneca AB
2	Opposition Ratiopharm 18 July, 2001 + English translation
3	Patentee reply 27 March, 2002.
4	Third party observation 30 May, 2002
5	Opponent submission 22 January, 2003 + English translation
6	Summons to oral proceedings 15 July, 2003
7	Opponent submission 21 and 23 October 2003
8	Patentee reply 24 October, 2003.
9	Information EPO 26 November, 2003.
10	Written decision from EPO, "when available"